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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,057	06/26/2001	Roberto Alcantara Martins Zucchetti	32286R006	6856

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EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/09/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/786,057

Applicant(s)

ZUCCHETTI ET AL.

Examiner

Clinton Ostrup

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/27/03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

Art Unit: 1614

## **DETAILED ACTION**

Claims 1-20 are pending in this application.

### **Response to Applicant's Arguments/Amendment**

#### **Claim Objection**

Applicant's amendment filed June 27, 2003, Paper No. 17, to the objection of claims 17-18 has made the objection moot. Therefore, the said objection has been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

Applicant's arguments and amendment filed June 27, 2003, Paper No. 17, to the rejection of claim 5 under 35 U.S.C. 112, second paragraph have been fully considered, however, the arguments and the amendment have not made the rejection moot. Therefore, the said rejection has been MAINTAINED for the reasons set forth in the Office Actions mailed December 5, 2001, Paper No. 7, July 1, 2002, Paper No. 10, December 26, 2002, Paper No. 13, and those found below.

Applicant argues that those skilled in the art would readily appreciate what is intended by the terms questioned by the Office Action and argue that the Examiner appears to agree that those of skill in the art would understand what is intended by the terms "skin structures" and "micronutrients" because that Advisory Action states 'It would have be [sic] obvious to substitute known ingredients which are being used for their art recognized purpose such as, skin structures, micronutrients...' The examiner respectfully disagrees. As discussed in the Advisory action, the "metes and bounds of what constitutes 'skin structures', 'micronutrients of the skin', and 'sensorial agents' is

Art Unit: 1614

not readily apparent to the skilled artisan and although the skilled artisan would appreciate the two examples of 'skin structures', one example of 'skin micronutrients', and two examples of 'sensorial agents' as such, the skilled artisan would not recognize what does and what does not constitute 'skin structures', 'micronutrients of the skin', and 'sensorial agents'. Moreover, as discussed in the previous Office Action, the claims are interpreted in light of the specification; limitations from the specification are not read into the claims."

***Claim Rejections - 35 USC § 103***

Applicant's arguments and amendment filed June 27, 2003, Paper No. 17, to the rejection of claims 1-18 under 35 U.S.C. 103(a), have been fully considered, however, the arguments and the amendment have not made the rejection moot. Therefore, the said rejection has been MAINTAINED with respect to claims 1-18 and further applied to claims 19-20, for the reasons set forth in the Office Actions mailed December 5, 2001, Paper No. 7, July 1, 2002, Paper No. 10, December 26, 2002, Paper No. 13, and those found below.

Applicant argues that they "have discovered a way to achieve a system which is capable of providing stability to the vitamin C in an aqueous medium through the addition of PVA, which polymer forms a network within the microcapsule thus avoiding the diffusion of vitamin A and vitamin C to the bulk formulation. However, none of the instant claims require the addition of said polymer, thus these arguments are not commensurate with the claims.

Art Unit: 1614

Applicants further argue that in their invention, "the vitamin A and C are employed within specific mass/mass ratios, however, none of the instant claims require mass to mass ratios. However, Claims 2-5, 8-18, and 20 do require specific percent weight concentrations. However differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See: *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). In the instant case, Rinaldi et al., soft gel capsules comprising microcapsules comprising Ascorbic acid and microcapsules comprising Vitamin A and Vitamin E.

Applicants argue that their microcapsules "ensure the vitamins will permeate the skin and reach their target sites, wherein these microcapsules are broken through enzymatic reactions, thus releasing the vitamins directly in the skin inner part, however, none of the instant claims require such limitations, thus, these arguments are not commensurate with what is claimed instantly in claims 1-20.

Applicant argues that the examiner has failed to establish a proper *prima facie* case of obviousness because the examiner has failed to establish the requisite motivation to those skilled in the art to modify the invention of Rinaldi with the teachings of Huc and because the combination of Rinaldi and Huc teach away from each other, there is also no expectation of success. Applicant argues that Rinaldi teaches soft gels are not compatible with water, as the water will degrade the gelatin shell and Huc

Art Unit: 1614

teaches using particles, which are biocompatible because they are made of atecollagen (a collagen derivative).

Applicants' argument that the soft gels of Rinaldi would not be compatible with water because the water will degrade the gelatin shell, has not been found convincing because Rinaldi teaches microspheres comprising vitamins, which are then filled into the soft gel capsules. Huc teaches the motivation to use biodegradable and biocompatible microspheres which offer the "protection of the active principle in a finished formulation" and it would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the microspheres of Huc, for those of Rinaldi, because of the reasonable expectation that the active principle could be microencapsulated using biodegradable microcapsules as taught Huc.

The motivation for doing so would be the reasonable expectation of obtaining a composition comprising microencapsulated active ingredients, which are not toxic, into microspheres that improve bioavailability and protect the microencapsulated active principle.

Therefore applicants' arguments have not been found convincing and the rejection of claims 1-18 has been MAINTAINED and applied to claims 19-20.

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1614

Claims 5-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite because it is unclear what is meant by the following terms: skin structures, micronutrients of the skin, and sensorial agents. These terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Any remaining claims are rejected as depending on indefinite base claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rinaldi et al **5,891,470** and further in view of Huc et al., 5,395,620.

Rinaldi et al teach soft gel formulations comprising retinol-impregnated microparticles and ascorbic acid, which may be present as ascorbic acid-impregnated microparticles and/or within the emulsion. See: col. 1, line 5 – col. 2, line 10 and abstract. The reference teaches how to make the microparticles and also describes how the retinol will frequently will be a commercial blend containing antioxidants such as, vitamin E. See: col. 3, line 39 – col. 4, line 56. The reference describes an emulsion formulation comprising amounts of retinol, ascorbic acid, and antioxidants in amounts, which overlap those of instant claims 2-6. See: col. 6, line 29 – col. 7, line 41.

Art Unit: 1614

Rinaldi et al specifically teach combining ascorbic acid-impregnated particles and retinol-impregnated particles comprising a retinol blend, tocopheryl acetate, ascorbic acid, disodium EDTA, and propyl gallate, together to obtain a soft gel capsule. See: col. 7, lines 42 – col. 9, line 30. Rinaldi et al., teach EDTA and cyclomethicone in the soft gel capsules comprising microcapsules of retinol and microcapsules of ascorbic acid, thus teaching the specific ingredients of instant claims 5, 13, and 17. See: Example 3. The reference teaches BHT as a useful oil-soluble antioxidant and teaches glycerin in the first phase of the emulsion. See: col. 6, line 59 – col. 7, line 9.

The primary reference teaches compositions comprising microcapsules comprising Vitamin A, Vitamin C, and Vitamin E is a soft gel capsule with microcapsules comprising Vitamin C, however, the reference does not specifically teach the microcapsules as being biologically active as claimed instantly in claim 1-18 or the specific ingredients of instant claims 8, 9, 12, 14, and 15-16.

Huc et al., 5,395,620 teaches biodegradable microcapsules that are particularly useful for cosmetics because they improve they bioavailability and protection of the active principle. The secondary reference specifically teaches the microencapsulation of hydrophilic compounds such as, Vitamin C, and hydrophobic compounds such as, several types of oils. The secondary reference teaches problems associated with microcapsules made from synthetic polymers and describes the benefits associated with biodegradable polymers. See: col. 1, lines 10-39; col.2, line 38 – col.3, line 8; Examples 1-7, and abstract.



Art Unit: 1614

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the microencapsulated compositions of Rinaldi et al., by using a biodegradable microcapsules as taught Rinaldi et al., because of the expectation of obtaining a composition comprising microencapsulated active ingredients which are not toxic and improve bioavailability and protect the microencapsulated active principle. It would have also be obvious to substitute known ingredients which are being used for their art recognized purpose such as, skin structures, micronutrients, emollients, sun protection factors, emulsifiers, and thickeners for another, because of the reasonable expectation of obtaining compositions with similar chemical properties.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup  
Examiner  
Art Unit 1614



Application/Control Number: 09/786,057  
Art Unit: 1614

Page 9

Frederick Krass  
Primary Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to read 'F. Krass', written over the printed name.